



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,652	10/17/2001	Mark W. Kroll	SJI-012US	7570

7590

06/22/2004

Pacesetter Inc
15900 Valley View Court
Sylmar, CA 91392-9221

EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
3762	

S

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,652

Applicant(s)

KROLL, MARK W.

Examiner

Mark W Bockelman

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 3762

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-6, 8-12, 14-16, 23-24, 26-27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by de Coriolis et al. USPN 5,674,250.

De Coriolis et al teach a device that performs the method of adjusting cardioverting (defibrillating) shock energy in an atrial defibrillator (column 1 line 9) based upon data stored in memory. The device teaches the monitoring of and tracking of atrial fibrillation indicators (column 6 lines 7-12) and tracking of R-R time intervals to determine whether they fall within a predetermined range (column 6 lines 13- 21) to determine whether a defibrillation shock needs to be applied. The time intervals may be stored in memory (see column 5 lines 25+). In addition, the device monitors and tracks the applied voltages as well as their success and keeps track of the number of successes. (column 6 lines 22- 43). The atrial fibrillation indicator, the R-R interval data, and the heart's response (defibrillation termination) to applied voltage provide cardiac data to be analyzed

Art Unit: 3762

by the microprocessor. After a number of cardioverting attempts at a particular voltage have been scored, the device performs a statistical analysis to determine the success rate in terms of success percentage for the applied voltage (column 6 lines 44-49). The device then compares the current voltages with the success rate with current acceptable limits and increments or decrements the shock energy level based upon the the cardiac data which offers an improved DFSE which can be adjusted based upon the limits selected. The adjusted voltage is applied to the next defibrillation detection. Other variations are discussed in column 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 17-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Caussey III USPN 5,554,174 (alone or in view of de Coriolis et al USPN 5,674,250). Caussey teaches a device for performing a method of adjusting a shock energy applied to terminate a ventricular defibrillation. The device monitors and tracks the cardiac data that includes the time of onset of fibrillation in the ventricle by use of a timer

Art Unit: 3762

(column 9 line 57). In conjunction with the time since onset and based upon the forecasted time to therapy) charge remaining of the battery) and a predetermined critical time, the device analyzes the cardiac data (time to therapy from onset of defibrillation) statistically (by use of tables) evaluates the shock delivery value necessary to provide a high probability of success. The algorithm is performed by a microprocessor which reads the program from a computer readable medium.

While the examiner considers Causey to meet the claim limitations, the examiner would also considered it obvious to use the shock success determination techniques of de Coriolis et al to further help conserve battery power and to automatically adjust the shock energies on the basis of time as well as on the basis of the response of the individual treated.

Claims 7, 3, 25, 30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over de Coriolis et al (alone or further in view of Causey, III). Since de Coriolis bases the determination of shock energy delivery on the success of previous shock data successfulness, the cardiac data is based upon cardiac rate, i.e. fibrillation or defibrillation. Alternatively to have include the "time to therapy" as demonstrated in Causey which is based upon monitoring fibrillation onset so as to conserve battery power would have been obvious.

Art Unit: 3762

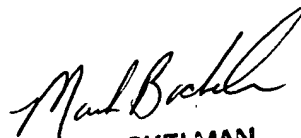
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

June 21, 2004


MARK BOCKELMAN
PRIMARY EXAMINER